

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Michael SCHIRNER et al.

Confirmation No.: 6769

Serial No.: 10/088,866

Examiner: HUFF, Sheela Jitendra

Filed: July 2, 2002

Group Art Unit: 1642

Title: ANTIBODY-DYE CONJUGATES FOR BINDING TO TARGET STRUCTURES OF ANGIOGENESIS IN ORDER TO INTRAOPERATIVELY DEPICT TUMOR PERIPHERIES

**REPLY**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The following is responsive to the office action of November 30, 2007.

It is respectfully submitted that the rejection under 35 USC 112 is completely untenable at least because the antibody L19 is per se conventional. There is no need to provide any information regarding enablement of a fully conventional component. See especially Neri 2003/0045681 which describes in detail how to prepare this single chain antibody. Note the latter point, that L19 is a single chain antibody. It is such antibody which is the subject of the rejected claims. Whereas applicants may be reciting “the entire antibody,” as the examiner indicates, this entire antibody is a single chain antibody. Thus, the examiner’s comments are irrelevant. Similarly, the existence of the deposit, while factual, is in essence irrelevant.

Both anticipation rejections are untenable. The examiner is ignoring the fact that the R<sub>1</sub> and R<sub>2</sub> groups do not encompass the corresponding groups of Cy7 and Cy5 and that the L group of the claims does not permit direct attachment of SO<sub>3</sub>. There is no anticipation.

As for the obviousness rejections, applicants hereby incorporate by reference all the previous arguments, including those based on the declaration. The examiner's three points with respect to the declaration do not justify maintenance of the rejection.

Use of the symbol "A" in the declaration makes clear that the antibody was the same for all five conjugates. In fact, this antibody is L19. Apologies are due to the examiner for the confusing presentation.

The examiner's objections based on certain generic disclosures in Licha and Viti are also untenable. Whereas Licha might state generically that the dyes it discloses yield highly sensitive, detectable fluorescent signals, this tells a skilled worker absolutely nothing regarding how such signals would compare with a conventional dye such as Cy7 tested in the declaration. In other words, Licha does not state that its dyes in comparison to conventional dyes such as Cy7 and/or Cy5 have higher fluorescence signals. It merely states that in comparison to nothing in particular, its dyes have highly sensitive signals. The same may be stated in general for the dyes Cy5 and Cy7. What is needed (and what has been provided) is a side-by-side comparison of the Licha et al. dyes with the closest prior art dye. This has been provided and established of record as providing unexpected advantages.

The same sentiments apply to the relied on statement in Viti. The latter relates in general to the high affinity of its antibody, L19. Nevertheless, in the data it is established that the L19 conjugates with the dyes of the invention have unexpected advantages in comparison to conjugates with the closest prior art dye, Cy7. Nothing in Viti leads one to expect that the immunoreactivity of the invention conjugates would be better than the immunoreactivity of conjugates with the prior art dye. If anything, Viti would lead a skilled worker to expect that all of the conjugates tested in the declaration would have the same high affinity. Thus, Viti supports the unexpectedness of the results shown in the declaration. Similarly, with respect to Licha, the latter provides no basis on which to expect that its dyes and antibody conjugates would have signals better than provided by corresponding conjugates with prior art dyes. As established of record, in fact, the claimed conjugates do have better signals as measured by the reported quantum yields.

As can be seen, the rejections are untenable and should be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

/Anthony J. Zelano/

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